MEDICAL MUTUAL®

Drug Policy

Policy:	Mavenclad (cladribine) oral dosage forms	Annual Review Date: 11/21/2023 Last Revised Date: 11/21/2023

OVERVIEW

Mavenclad, a purine antimetabolite, is indicated for the treatment of relapsing forms of **multiple sclerosis** (MS), to include relapsing remitting disease, and active secondary progressive disease, in adults.[1] Due to its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternative drug for the treatment of MS.[1] A limitation of use is that Mavenclad is not recommended for use in patients with clinically isolated syndrome because of its safety profile.

POLICY STATEMENT

This policy involves the use of Mavenclad. Prior authorization is recommended for pharmacy benefit coverage of Mavenclad. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Mavenclad as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Mavenclad be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Mavenclad is recommended in those who meet the following criteria:

1. **Multiple Sclerosis (MS), Initial Therapy**
   Criteria. *Patient must meet the following criteria (A, B, and C):*
   - A. The patient has a relapsing form of MS to include relapsing-remitting disease or active secondary progressive disease; AND
   - B. The patient is 18 years of age or older; AND
   - C. The agent is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis

2. **Multiple Sclerosis (MS), Continuing Therapy**
   Criteria. *Patient must meet the following criteria (A, B, C, D, and E):*

A. The patient has a relapsing form of MS to include relapsing-remitting disease or active secondary progressive disease; AND
B. The agent is prescribed by or in consultation with neurologist or a physician who specializes in the treatment of multiple sclerosis; AND
C. The patient has had beneficial response to the requested medication; AND
   Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions]; stabilization or reduced worsening on the Expanded Disability State Scale (EDSS) score; achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4; improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale; reduction or absence of relapses; improvement or maintenance on the six-minute walk test or 12-Item MS Walking Scale; improvement on the Multiple Sclerosis Functional Composite (MSFC) score; and/or attenuation of brain volume loss.
D. The patient has only received the first course (consisting of two cycles 23-27 days apart) of Mavenclad at least 43 weeks prior to the anticipated start of the second course [documentation required]; AND
E. The patient will not receive more than two courses (each consisting of two cycles given 23-27 days apart) of Mavenclad for life; AND

Initial Approval/ Extended Approval.
A) *Initial Approval:* 60 days
B) *Extended Approval:* 60 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Mavenclad has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Clinically Isolated Syndrome.** Mavenclad is not recommended for use in patients with clinically isolated syndrome due to its safety profile.

2. **Current Use with Other Disease-Modifying Agents Used for Multiple Sclerosis.** These agents are not indicated for use in combination (See Appendix for examples). Additional data are required to determine if use of disease-modifying multiple sclerosis agents in combination is safe and provides added efficacy.

3. **Non-Relapsing Forms of Multiple Sclerosis.** The efficacy of Mavenclad has not been established in patients with multiple sclerosis with non-relapsing forms of the disease.[1]
   Note: An example of a non-relapsing form of multiple sclerosis is primary progressive multiple sclerosis.

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Mavenclad® tablets [prescribing information]. Rockland, MA: EMD Serono; September 2022.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. September 2019. Available at: http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed on October 22, 2022.
3. McGinley MP, Goldschmidt C, Rae-Grant AD. Diagnosis and treatment of multiple sclerosis. A review. *JAMA*. 2021;325(8):765-779.
4. No authors listed. Drugs for multiple sclerosis. *Med Lett Drugs Ther*. 2021;63(1620):42-48.
5. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
6. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173.

APPENDIX

Medication	Mode of Administration
Aubagio® (teriflunomide tablets, generic)	Oral
Avonex® (interferon beta-1a intramuscular injection)	Injection (self-administered)
Bafiertam® (monomethyl fumarate delayed-release capsules)	Oral
Betaseron® (interferon beta-1b subcutaneous injection)	Injection (self-administered)
Briumvi™ (ublituximab-xiij intravenous infusion)	Intravenous infusion
Copaxone® (glatiramer acetate subcutaneous injection, generic)	Injection (self-administered)
Extavia® (interferon beta-1b subcutaneous injection)	Injection (self-administered)
Gilenya® (fingolimod capsules, generic)	Oral
Glatopa® (glatiramer acetate subcutaneous injection)	Injection (self-administered)
Kesimpta® (ofatumumab subcutaneous injection)	Injection (self-administered)
Lemtrada® (alemtuzumab intravenous infusion)	Intravenous infusion
Mavenclad® (cladribine tablets)	Oral
Mayzent® (siponimod tablets)	Oral
Ocrevus® (ocrelizumab intravenous infusion)	Intravenous infusion
Plegridy® (peginterferon beta-1a subcutaneous or intramuscular injection)	Injection (self-administered)
Ponvory™ (ponesimod tablets)	Oral
Rebif® (interferon beta-1a subcutaneous injection)	Injection (self-administered)
Tascenso ODT™ (fingolimod orally disintegrating tablets)	Oral

Tecfidera® (dimethyl fumarate delayed-release capsules, generic)	Oral
Tysabri® (natalizumab intravenous infusion)	Intravenous infusion
Vumerity® (diroximel fumarate delayed-release capsules)	Oral
Zeposia® (ozanimod capsules)	Oral